UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

ACRUX DDS PTY LTD.,	)	
	)	
Plaintiff,	)	
v.	)	Cause No. 1:17-CV-3824
	)	
SANDOZ, INC.,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Acrux DDS Pty Ltd. ("Acrux") ("Plaintiff") files this Complaint for patent infringement against Sandoz, Inc. ("Defendant") under 35 U.S.C. § 271. This patent action concerns the Abbreviated New Drug Application ("ANDA") No. 207337 submitted by Sandoz to the U.S. Food and Drug Administration.

THE PARTIES

1. Acrux is an Australian corporation that has its corporate offices and principal place of business at 103-113 Stanley Street, West Melbourne VIC 3003, Australia. Acrux is engaged in the development and commercialization of pharmaceutical products for sale throughout the world.

2. On information and belief, Sandoz is a company organized and existing under the laws of the State of Colorado, with a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

3. On information and belief, Sandoz is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the

State of Indiana and throughout the United States, alone and/or through its wholly-owned subsidiaries and agents.

NATURE OF THE ACTION

4. This is an action for infringement of U.S. Patent Nos. 8,435,944 ("the '944 patent"), 8,993,520 ("the '520 patent"), and 9,180,194 ("the '194 patent) (collectively, "the asserted patents"). This action relates to ANDA No. 207337 ("Sandoz's ANDA") submitted in the name of Sandoz, Inc. to the FDA for approval to market a generic version of Axiron® (testosterone) product, the reference listed drug ("RLD") covered by the asserted patents. In submitting ANDA No. 207337, Sandoz submitted certifications against the asserted patents, which constitutes an act of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

6. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

7. Upon information and belief, venue and jurisdiction are proper for this proceeding.

8. On information and belief, this Court has personal jurisdiction over Defendant because it regularly and continuously transacts business within the State of Indiana. On information and belief, Defendant develops, manufactures, markets, and sells pharmaceutical products throughout the United States, including the State of Indiana. On information and belief, Defendant maintains a broad distributorship network within Indiana.

9. On information and belief, Defendant derives substantial revenue from Indiana drug sales and has availed itself of the privilege of conducting business within the State of Indiana.

10. Sandoz's press releases describe Sandoz as "a global leader in generic pharmaceuticals and biosimilars. . . . Our portfolio of approximately 1000 molecules, covering all major therapeutic areas, accounted for 2016 sales of USD 10.1 billion. In 2016, our products reached well over 500 million patients and we aspire to reach one billion." *E.g.*, https://www.us.sandoz.com/news/media-releases/sandoz-proposed-biosimilar-rituximab-accepted-review-fda.

11. Defendant's website further states that "Our core business lies in developing, producing, and distributing high-quality medicines following the loss of their respective patent protection, thus helping secure access to affordable, quality healthcare for patients in the US." https://www.us.sandoz.com/our-work/quality-generics. On information and belief, Sandoz is distributing its pharmaceuticals in the State of Indiana.

12. On information and belief, Sandoz, either directly or through distributors, currently sells significant quantities of generic drug products in the State of Indiana. Among the hundreds of products available, for example, are Sandoz's Alprazolam (generic for Xanax®), Bupropion Hydrocloride (generic for Wellbutrin®), Fluoxetine (generic for Prozac®), Omeprazole (generic for Prilosec®), amoxicillin, cyclosporine, and penicillin. A list of generic products sold by Sandoz in the United States can be found at https://www.us.sandoz.com/patients-customers/product-catalog.

13. Sandoz, through its website, solicits customers and potential from across the U.S., including in the Southern District of Indiana, who can search and access prescribing information

for Sandoz's full product line and learn how to return Sandoz's products. https://www.us.sandoz.com/patients-customers/information-customers.

14. Sandoz develops and manufactures pharmaceutical products for the United States market, including the State of Indiana. Sandoz, either directly or through distributors, sells products to national and regional retail drug, supermarket, and mass merchandise chains in the State of Indiana, and derive substantial revenue from these sales.

15. On information and belief, Sandoz prepared and submitted of ANDA No. 207337 and Sandoz will directly benefit from the approval of ANDA No. 207337.

16. This Court has personal jurisdiction over Sandoz by virtue of its course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in the State of Indiana. Defendant "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, the Southern District of Indiana and elsewhere. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 759 (Fed. Cir. 2016). Defendant's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Id.* at 760. On information and belief, Defendant "intends to direct sales of its drugs into [Indiana], among other places, once it has the requested FDA approval to market them." *Id.* at 758. On information and belief, Sandoz will engage in marketing of the proposed Sandoz ANDA product in the State of Indiana upon approval of the Sandoz ANDA.

17. Sandoz's ANDA filing, including its Paragraph IV certifications regarding the '944, '520, and '194 patents, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities by Defendant in this District. "[T]he

minimum-contacts standard is satisfied by the particular actions [Defendant] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in" this District. *Id.* at 760. Exercising personal jurisdiction over Defendant in this District would not be unreasonable given its contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

18. As further evidence of personal jurisdiction, Sandoz has availed themselves of this forum previously for the purpose of litigating a patent dispute, including asserting counterclaims in this Judicial District in several cases, including *Alcon Research, Ltd. v. Sandoz Inc.*, No. 1:10-cv-00106 (S.D. Ind. 2010); *Eli Lilly and Co. v. Sandoz, Inc.*, No. 1:09-cv-01282 (S.D. Ind. 2009); *Alcon Research, Ltd. v. Sandoz Inc.*, No. 1:09-cv-00103 (S.D. Ind. 2009); *Alcon Mfg., Ltd. v. Barr Labs, Inc.*, No. 1:07-cv-01377 (S.D. Ind. 2007). Sandoz has been involved in litigation in Indiana for products liability cases as well. In *Nelson v. Sandoz Pharm. Corp.*, the injured plaintiff sued Sandoz in the United States District Court for the District of New Jersey. 288 F.3d 954, 960 (7th Cir. 2002). But Sandoz moved to transfer the action to the Northern District of Indiana where the plaintiff was located. *Id.* Thus, Sandoz not only litigated that case to its resolution in Indiana and through the appeals process in the Seventh Circuit without contesting jurisdiction, but it also sought out Indiana in the first place as a forum for its litigation. Sandoz also litigated in *Hagerman v. Alza Corp*, 1:09-CV-187-PPS-PRC, in the Northern District of Indiana and *Carlson v. Alza Corp.*, 1:09-cv-0809 SEB-DML, in the Southern District of Indiana.

19. Thus, the exercise of personal jurisdiction over Sandoz is proper.

FACTUAL BACKGROUND

A. The Asserted Patents

1. The ’944 Patent

20. United States Patent No. 8,435,944 (“the ’944 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on May 7, 2013. The ’944 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male comprising applying a transdermal drug delivery composition that contains testosterone. The ’944 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) in connection with Axiron®. A true and correct copy of the ’944 patent is attached as Exhibit A. Since its date of issue, Acrux has been, and continues to be, the owner of the ’944 patent.

2. The ’520 Patent

21. United States Patent No. 8,993,520 (“the ’520 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the PTO on March 31, 2015. The ’520 patent claims, *inter alia*, methods of increasing the testosterone blood level of an adult male subject comprising applying a transdermal drug delivery composition. The ’520 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the ’520 patent is attached as Exhibit B. Since its date of issue, Acrux has been, and continues to be, the owner of the ’520 patent.

3. The ’194 Patent

22. United States Patent No. 9,180,194 (“the ’194 patent”), titled “Method and Composition for Transdermal Drug Delivery,” was duly and legally issued by the PTO on November 10, 2015. The ’194 patent claims, *inter alia*, methods of increasing the testosterone

blood level of an adult male subject comprising applying a transdermal drug delivery composition. The '194 patent is listed in the Orange Book in connection with Axiron®. A true and correct copy of the '194 patent is attached as Exhibit C. Since its date of issue, Acrux has been, and continues to be, the owner of the '194 patent.

B. Infringement by Sandoz

23. Sandoz filed or caused to be filed with the FDA ANDA No. 207337 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of a transdermal "Testosterone Topical Solution, 30 mg/1.5mL" ("Sandoz's Generic Product") in the United States before the expiration of the '944, '520, and '194 patents.

24. Sandoz's ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certifications"), alleging that the claims of the '944, '520, and '194 patents are invalid, unenforceable, and/or would not be infringed by Sandoz's Generic Product.

25. Sandoz sent or caused to be sent to Acrux a letter dated September 11, 2017 ("Notice Letter"), notifying Acrux that Sandoz's ANDA includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Sandoz's Generic Product before the expiration of the '944, '520, and '194 patents, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B).

26. Sandoz's Notice Letter states that: "The ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and (2)(A), and contains paragraph IV certifications to obtain approval to engage in the commercial manufacture, use or sale of testosterone solution; metered; transdermal; 30 mg/1.5mL actuation, before the expiration of the '944, '878, '520, '194, and '586 patents, which are listed in the Patent and Exclusivity Information Addendum of FDA's publication, *Approved*

Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book) with respect to Axiron® (testosterone solution; metered; transdermal; 30 mg/1.5mL actuation.)"

27. Sandoz's Notice Letter also states: "Sandoz alleges, and has certified to FDA, that in Sandoz's opinion and to the best of its knowledge, the '944, '878, '520, '194, and '586 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug products described in Sandoz's ANDA."

28. The submission of Sandoz's to the FDA constitutes infringement by Defendant of the '944 patent, the '520 patent, and the '194 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Sandoz's Generic Product would infringe the '944 patent, the '520 patent, and the '194 patent under 35 U.S.C. § 271(a), (b), and/or (c).

29. Defendant knows and intends that physicians will prescribe and patients will take Sandoz's Generic Product for which approval is sought in ANDA No. 207337 and, therefore, will infringe at least one claim of the patents-in-suit.

30. Defendant had knowledge of the patents-in-suit, and by its promotional activities and proposed commercial manufacture, use, sale, offer for sale, or importation of Sandoz's Generic Product, knew or should know that it will aid and abet another's direct infringement of at least one of the claims of the patents-in-suit either literally or under the doctrine of equivalents.

31. Defendant plans to make, use, sell, offer to sell, and/or import Sandoz's Generic Product for uses that will infringe the patents-in-suit. Sandoz's Generic Product is a material part of these infringing uses and has no substantial non-infringing uses.

32. Acrux commenced this action within 45 days of receiving Sandoz's September 11, 2017, Notice Letter.

COUNT I FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,435,944)

33. Plaintiff incorporates by reference and realleges Paragraphs 1-32 above as though fully restated herein.

34. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207337 to the FDA seeking approval of Sandoz's Generic Product before expiration of the '944 patent was an act of infringement of the '944 patent by Defendant.

35. If ANDA No. 207337 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Sandoz's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '944 patent under 35 U.S.C. § 271.

36. Unless Defendant is enjoined by the Court, Plaintiff will be substantially and irreparably harmed by Defendant's infringement of the '944 patent. Plaintiff does not have an adequate remedy at law.

COUNT II FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,435,944)

37. Plaintiff incorporates by reference and realleges Paragraphs 1-36 above as though fully restated herein.

38. Defendant has knowledge of the '944 patent.

39. Upon FDA approval of ANDA No. 207337, Defendant will intentionally encourage acts of direct infringement of the '944 patent by others, with knowledge that its acts are encouraging infringement.

COUNT III FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,435,944)

40. Plaintiff incorporates by reference and realleges Paragraphs 1-39 above as though fully restated herein.

41. If ANDA No. 207337 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic Product.

42. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '944 patent.

43. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

COUNT IV FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 8,993,520)

44. Plaintiff incorporates by reference and realleges Paragraphs 1-43 above as though fully restated herein.

45. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207337 to the FDA seeking approval of Sandoz's Generic Product before expiration of the '520 patent was an act of infringement of the '520 patent by Defendant.

46. If ANDA No. 207337 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Sandoz's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '520 patent under 35 U.S.C. § 271.

47. Unless Defendant is enjoined by the Court, Plaintiff will be substantially and irreparably harmed by Defendant's infringement of the '520 patent. Plaintiff does not have an adequate remedy at law.

COUNT V FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 8,993,520)

48. Plaintiff incorporates by reference and realleges Paragraphs 1-47 above as though fully restated herein.

49. Defendant has knowledge of the '520 patent.

50. Upon FDA approval of ANDA No. 207337, Defendant will intentionally encourage acts of direct infringement of the '520 patent by others, with knowledge that its acts are encouraging infringement.

COUNT VI FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 8,993,520)

51. Plaintiff incorporates by reference and realleges Paragraphs 1-50 above as though fully restated herein.

52. If ANDA No. 207337 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic Product.

53. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '520 patent.

54. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

COUNT VII FOR PATENT INFRINGEMENT
(Direct Infringement of U.S. Patent No. 9,180,194)

55. Plaintiff incorporates by reference and realleges Paragraphs 1-54 above as though fully restated herein.

56. Pursuant to 35 U.S.C. § 271(e)(2), Defendant's submission of ANDA No. 207337 to the FDA seeking approval of Sandoz's Generic Product before expiration of the '194 patent was an act of infringement of the '194 patent by Defendant.

57. If ANDA No. 207337 is approved by the FDA, Defendant's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Sandoz's Generic Product would directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '194 patent under 35 U.S.C. § 271.

58. Unless Defendant is enjoined by the Court, Plaintiff will be substantially and irreparably harmed by Defendant's infringement of the '194 patent. Plaintiff does not have an adequate remedy at law.

COUNT VIII FOR PATENT INFRINGEMENT
(Inducement To Infringe U.S. Patent No. 9,180,194)

59. Plaintiff incorporates by reference and realleges Paragraphs 1-58 above as though fully restated herein.

60. Defendant has knowledge of the '194 patent.

61. Upon FDA approval of ANDA No. 207337, Defendant will intentionally encourage acts of direct infringement of the '194 patent by others, with knowledge that its acts are encouraging infringement.

COUNT IX FOR PATENT INFRINGEMENT
(Contributory Infringement of U.S. Patent No. 9,180,194)

62. Plaintiff incorporates by reference and realleges Paragraphs 1-61 above as though fully restated herein.

63. If ANDA No. 207337 is approved, Defendant intends to and will offer to sell, sell, or import into the United States Sandoz's Generic Product.

64. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '194 patent.

65. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

COUNT X FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,435,944)

66. Plaintiff incorporates by reference and realleges Paragraphs 1-65 above as though fully restated herein.

67. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

68. Defendant submitted ANDA No. 207337, seeking authorization to commercially manufacture, use, offer for sale, and sell Sandoz's Generic Product in the United States. Sandoz's Generic Product has no substantial non-infringing uses.

69. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic Product prior to expiration of the '944 patent.

70. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic Product upon receipt of final FDA approval of ANDA No. 207337, unless enjoined by the Court.

71. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Sandoz's Generic Product would infringe one or more claims of the '944 patent under 35 U.S.C. § 271(a), (b), and/or (c).

72. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Sandoz's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '944 patent.

73. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '944 patent.

74. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

75. There is a justiciable case or controversy between Plaintiff and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic Product according to ANDA No. 207337 would infringe one or more claims of the '944 patent.

76. If Defendant's infringement of the '944 patent is not enjoined, Plaintiff will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XI FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 8,993,520)

77. Plaintiff incorporates by reference and realleges Paragraphs 1-76 above as though fully restated herein.

78. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

79. Defendant submitted ANDA No. 207337, seeking authorization to commercially manufacture, use, offer for sale, and sell Sandoz's Generic Product in the United States. Sandoz's Generic Product has no substantial non-infringing uses.

80. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic Product prior to expiration of the '520 patent.

81. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic Product upon receipt of final FDA approval of ANDA No. 207337, unless enjoined by the Court.

82. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Sandoz's Generic Product would infringe one or more claims of the '520 patent under 35 U.S.C. § 271(a), (b), and/or (c).

83. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Sandoz's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '520 patent.

84. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '520 patent.

85. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

86. There is a justiciable case or controversy between Plaintiff and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic Product according to ANDA No. 207337 would infringe one or more claims of the '520 patent.

87. If Defendant's infringement of the '520 patent is not enjoined, Plaintiff will suffer substantial and irreparable harm from which there is no remedy at law.

COUNT XII FOR DECLARATORY JUDGMENT
(Infringement of U.S. Patent No. 9,180,194)

88. Plaintiff incorporates by reference and realleges Paragraphs 1-87 above as though fully restated herein.

89. This declaratory judgment claim arises under the United States Patent Laws, 35 U.S.C. § 100 *et seq*., including 35 U.S.C. § 271(a)-(c), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. Subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

90. Defendant submitted ANDA No. 207337, seeking authorization to commercially manufacture, use, offer for sale, and sell Sandoz's Generic Product in the United States. Sandoz's Generic Product has no substantial non-infringing uses.

91. Defendant has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import Sandoz's Generic Product prior to expiration of the '194 patent.

92. Defendant intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of Sandoz's Generic Product upon receipt of final FDA approval of ANDA No. 207337, unless enjoined by the Court.

93. Defendant's commercial manufacture, use, sale, or offer for sale within or importation into the United States of Sandoz's Generic Product would infringe one or more claims of the '194 patent under 35 U.S.C. § 271(a), (b), and/or (c).

94. Defendant's threatened actions in actively aiding, abetting, encouraging, and inducing sales of Sandoz's Generic Product would infringe and contribute to or induce direct infringement of one or more claims of the '194 patent.

95. On information and belief, Defendant has had and continues to have knowledge that Sandoz's Generic Product is especially adapted for a use that infringes the '194 patent.

96. On information and belief, Defendant has had and continues to have knowledge that there is no substantial non-infringing use for Sandoz's Generic Product.

97. There is a justiciable case or controversy between Plaintiff and Defendant regarding whether Defendant's commercial manufacture, use, sale, offer for sale, or importation into the United States of Sandoz's Generic Product according to ANDA No. 207337 would infringe one or more claims of the '194 patent.

98. If Defendant's infringement of the '194 patent is not enjoined, Plaintiff will suffer substantial and irreparable harm from which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court enter judgment in its favor as follows:

a) United States Patent Nos. 8,435,944, 8,993,520, and 9,180,194 are valid and enforceable;

b) Under 35 U.S.C. § 271(e)(2)(A), Defendant infringed United States Patent Nos. 8,435,944, 8,993,520, and 9,180,194 by submitting ANDA No. 207337 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, or import into the United States Sandoz's Generic Product prior to expiration of said patents;

c) Defendant's threatened acts of commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Sandoz's Generic Product prior to the expiration of United States Patent Nos. 8,435,944, 8,993,520, and 9,180,194 would constitute infringement of said patents;

d) The effective date of any FDA approval of Sandoz's Generic Product shall be no earlier than the latest of the expiration date of United States Patent Nos. 8,435,944, 8,993,520, and 9,180,194 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

e) Defendant, and all persons acting in concert with Defendant, shall be enjoined from commercially manufacturing, using, offering for sale, or selling Sandoz's Generic Product within the United States, or importing Sandoz's Generic Product into the United States, until the expiration of United States Patent Nos. 8,435,944, 8,993,520, and 9,180,194 in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

f) This is an exceptional case and Plaintiff should be awarded its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

g) Plaintiff is entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

h) Plaintiff is entitled to any further and additional relief that this Court deems just and proper.

/s/ Anne N. DePrez
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